II. REMARKS

Claims 1-5 and 33-36 are pending. No new matter is added.

Rejection under 35 U.S.C. § 112

Claims 1-5 and 33-36 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not complying with the enablement requirement. Specifically, the Office stated that *"While the state of the art and level of skill in the art with regard to determining the level of any particular transcription product is high, the unpredictability associated with correlating any compared level with a particular phenotype such as depression or stress is higher. Such unpredictability is demonstrated by the prior art, the post-filing art, and the instant specification...it is relevant to point out the unpredictability in extrapolating gene expression results among different organisms... it is relevant to point out the unpredictability in extrapolating gene expression results among different tissue types...It is thus unpredictable as to whether or not any non-mRNA analyte would in fact be predicative of mRNA expression...it is relevant to point out the unpredictability associated with gene expression comparisons...it is relevant to consider the breath of the claimed method in diagnosing stress or depression"*.

Applicants respectfully traverse. Applicants submit that a person skilled in the art is able to make and use the claimed invention, without undue experimentation, to diagnose depression or stress modulated by corticotropin releasing hormone (CRH) using the transcription level of SEQ ID NO.19, more commonly known in the art as 11β-hydroxysteroid dehydrogenase or 11β-HSD. It is known in the art that the CRH signaling network correlates to the development of depression/stress. One example is Applicants' work that transgenic mice overexpressing corticotrophin-releasing factor (CRF) are hyper-reactive to stressors and that the anxiogenic-like behaviors of the transgenic mice are reversed by CRF receptor antagonist. In the present application, Applicants found the transcript levels of several genes, including SEQ ID NO.19, were altered in transgenic mice showing depressed symptoms. Based on Applicants' findings and the knowledge at the time of filing, a person skilled in the art would readily make and use the claimed method to diagnose depression or stress modulated by CRH using the transcription level of 11β -HSD.

The Office relies on several references as indicative of the unpredictability of the claimed invention. Applicants submit that none of the references cited by the Office is relevant to CRH and their role in development of depression/stress. For example, the Office

cites Hoshikawa et al. 2002 in support of the rejection that *"whether or not any genes that are asserted to be related to stress in, for example, mouse are in fact applicable to predicting stress in any other non-mouse organism"* see page 5. However, Hoshikawa discloses hypoxia-induced gene expression in lungs of rats and mice. Hoshikawa does not disclose any other disorder such as depression nor the gene expression thereof. Additionally, the Office cites Chen et al. 2002 in support of the rejection that *"whether or not any non-mRNA analyte would in fact be predictive of mRNA expression"* see page 6. Applicants respectfully submit that Chen et al. studies gene expressions in lung cancer. Chen et al. does not disclose any other disorder such as depression nor the gene expression thereof. It is unreasonable to generalize specific studies of the cited references to unrelated biological conditions such as depression/stress modulated by CRH expression.

In veiw of the foregoing, the rejection is obviated. Resonsideration and withdrawal of the rejeciton under 35 U.S.C. § 112, first paragraph, are respectfully requested.

III. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the office require anything further, it is invited to contact applicants' representative at the telephone number below.

Respectfully submitted,

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